

REMARKS

Status of the Application

Claims 29, 30, 32, 35-36, 38, 41-42, 44, and 62-63 are pending.

Claim Amendments

Claim 29 has been added to recite 375 mg. Support for this amendment can be found in Table 9 on page 22 of the specification. No new matter has been added as a result of this amendment.

Claim Rejections – 35 U.S.C. Section 112

Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with the written description requirement. The Examiner says that a review of the instant specification, namely, page 6, lines 21-25, page 20, lines 3-16 and table II on page 31, reveals that the instant claim limitations “for achieving a balanced lipid alteration in a patient in need thereof”, “at least two formulations comprising” are not supported by the instant specification with respect to 500 mg and 1000 mg.” The Examiner says that instead, the new claim limitations are supported with at least two 750 mg formulations to achieve a daily dosage of 1500 mg but that the specification did not appear to support the at least two with respect to 500 mg and 1000 mg to achieve a daily dose of 1500 mg. The Examiner also refers to page 20 of the specification where it states that two tablets of 500 mg for a 1000 mg dose, two tablets of 750 mg for 1500 mg dose and 2 tablets of 1000 mg for a 2000 mg dose and that this is not the same as what is claimed. Applicants respectfully traverse.

Applicants respectfully direct the Examiner’s attention to Table 9 on page 22 of the specification. This Table shows a number of daily doses in the amount of 1500 mg. Specifically, this table shows that tablets of 375 mg, 500 mg and 750 mg were used to achieve a daily dose of 1500 mg. Thus, Applicants submit that the description provided in this table in connection with the rest of the application clearly allows one skilled in the art to recognize what the inventors have claimed pursuant to the requirements of 35 U.S.C. Section 112, first paragraph. In view of the aforementioned arguments, Applicants submit that this rejection is now moot and should be withdrawn.

Claim Rejections – 35 U.S.C. Section 103(a)

Claims 29, 30, 32, 34-36, 38, 41-42, 44, 62 and 63 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 5,126,145 (Evenstad et al.) (“145”) or U.S. Patent No. 5,268,181 to O’Neill et al. (“181”). Applicants respectfully traverse.

As discussed in Applicants last Amendment filed on April 8, 2008, claim 29 has (in the Amendment filed on April 8, 2008) been amended to make it commensurate with the scope of the Bova declaration filed in the Amendment on December 14, 2007. In view thereof, Applicants submit that they have now effectively removed the '181 patent as a reference. With respect to the '145 patent, as also discussed during the interview, the '145 patent does not teach or disclose using the described 250, 500 or 750 formulations for treating any condition or disease. Moreover, the '145 patent does not teach orally administering to a patient once per day at night or during the evening at least two intermediate formulations to obtain a dose of at least 1500 mg for the purpose of achieving a balanced lipid alteration in said patient. Therefore, in view of the aforementioned arguments, this rejection is now believed to be moot and should be withdrawn.

REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned at

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